



UNIVERSITY OF KWAZULU-NATAL BIOMEDICAL RESEARCH ETHICS COMMITTEE (BREC) TERMS OF REFERENCE

1. INTRODUCTION

The University of KwaZulu-Natal Biomedical Research Ethics Committee's (hereafter BREC) Terms of Reference are aligned with and with the National Health Act 61/2003 and the Department of Health's Ethics in Health Research Guidelines (March 2015) and the University of KwaZulu-Natal's Research Policy V: Research Ethics. The National Health Act per s 73 requires institutions to establish RECs which are registered with the NHREC and requires all 'health research' involving human participants to undergo prior ethics review by a registered research ethics committee. Such committees are registered by the National Health Research Ethics Council after an assessment of eligibility and compliance with the governing legal and ethics framework.

2. AUTHORITY

The University of KwaZulu-Natal BREC is established as a committee of the University and the essential purpose of BREC is to protect the dignity, rights, safety, and well-being of all human participants in health-related research. BREC will do this through independent, prospective and ongoing ethics review of all health research projects undertaken by members of staff, registered students and affiliates of the University. Special attention will be paid to research that may include vulnerable participants (Appendix A). The Committee is available to review, advise on, and approve or reject research protocols involving human participants submitted to it by researchers at UKZN and, at the discretion of the Chair, in the province of KwaZulu-Natal or any other province in the Republic of South Africa who are not UKZN staff members, students or affiliates.

Research to be reviewed will be in accordance with the provisions of the National Health Act. In addition, when the University undertakes non-exempt human participant research that is supported by the US Department of Health and Human Services (HHS), the University and BREC will ensure that the HHS protection of human participants' regulations are adhered to.

The UKZN BREC is registered with the National Research Ethics Council (NHREC) in accordance with the National Health Act 61/2003. Its registration number is REC - 290409-009. The UKZN BREC is also registered with the US Office of Human Research Protections and has Federal-Wide Assurance (FWA) Assurance number 678, Institution number IORG 0000923 and IRB number 00001293.

3. MANDATE

The UKZN BREC is mandated to fulfil its functions in accordance with the National Health Act 61/2003 as outlined in the Department of Health 'Ethics in Health Research' guidelines (2015). It reports annually to the National Research Ethics Council (NHREC) and to the DVC (Research) at UKZN.

4. SCOPE OF OPERATIONS

The UKZN BREC must

- establish Standard Operating Procedures (SOPs) that systematically describe all the processes and procedures involved in its work including its institutional arrangements and reporting obligations. It must ensure that the SOPs are systematically reviewed every three to four years or more frequently as necessitated by research ethics changes. The SOPs must be available to all members of the University community and the general public
- establish appropriate documentation (application forms, guidance documents, review guidance, information & consent document guidance as well as report templates amongst others) to facilitate appropriate processing of applications and to assist researchers to comply with requirements
- conduct rigorous ethics review, prospectively, of all health or health-related research proposals to ensure that welfare and other interests of participants, and researchers, are properly protected and that the proposed research is compliant with ethical norms and standards (retrospective review is not permitted)
- ensure that research proposals are scientifically sound and feasible
- decide whether to approve, to require amendments or to reject the proposals for lack of compliance with scientific or ethics norms and standards
- ensure appropriate reporting occurs to fulfil the oversight obligation of the UKZN BREC to monitor welfare interests of participants
- in consultation with BREC, the BREC chair may assist the University Research Office in adjudicating complaints of research ethics transgressions and/or research misconduct by University members and other researchers whose protocols have been approved by BREC. Any health sciences related research which requires participant protection and is conducted by a university staff member or student without prior ethics approval will also be regarded as an ethics transgression necessitating such action by the University Research Office.
- These Terms of Reference may only be revised through the approval process described below.

5. TERMS OF REFERENCE APPROVAL PROCESS

These Terms of Reference may only be revised after approval by BREC, the DVC (Research), and the UKZN Senate.

These Terms of Reference were approved by BREC on 12 March 2019 and by the DVC (Research) on 02 September 2020 and the UKZN Senate on 18 November 2020.

Signed by Chair: BREC

12 March 2019

Signed by DVC Research

02 September 2020

Approved by Senate

18 November 2020